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EXAMINER
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ART UNIT 1807 | PAPER NUMBER 19

DATE MAILED: 10/28/92

[illegible]

☒ This application has been examined ☒ Responsive to communication filed on Ind on 10/23/92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 10-19, 22, 24-26, 36-42, 45-48, 51-53, 74, 75, 102, 103, and 127-130 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-9, 20, 21, 23, 27-35, 43, 44, 49, 50, 54-73, 76-101, and 104-126 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 10-19, 22, 24-26, 36-42, 45-48, 51-53, 74, 75, 102, 103, and 127-130 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received. ☐ not been received.
    ☐ been filed in parent application, serial no. _____; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

Applicants' arguments discussed during the interview of which a summary was mailed 10/26/92 have been fully considered. In the interest of forwarding prosecution and considering the clear intent of applicants to resolve the previously applied rejections, the Examiner has reconsidered the instant application. This reconsideration has resulted in the application of added rejections as summarized herein. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Due to the application of new grounds of rejection as summarized herein, the Final Rejection status as given in the previous office action mailed 7/28/92 is hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 11, 17-19, 22, 24-26, 36, 37, 42, 46-48, 51-53, 74, 75, 102, 103, and 127-130 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the CML diagnostic detection of mutations that occur in at least one of the breakpoint regions instantly disclosed as being contained in the BCR or ABL regions. These regions are

instantly disclosed as being diagnostic of CML whereas mutations in other regions are not sufficiently disclosed as to their conclusive diagnostic value. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 10-19, 22, 24-26, 36-41, 74, 75, 102, 103, and 127-130 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 and claims dependent therefrom are vague and indefinite in that line 9 states that the claimed method is diagnostic for CML whereas, in contrast, claim 10 lacks any step that accomplishes CML diagnosis. For example, the last two lines of claim 10 practices the visualization of hybridized labeled fragments but lacks any CML diagnostic practice. CML diagnosis requires more than simple visualization. For example, there must be some diagnostic distinction or pattern that is recognizable from the visualized nucleic acids. Stated in another way, what visual pattern is diagnostic for CML versus the pattern that is not diagnostic for CML? Several claims contain phrases directed to staining patterns such as claims 13 and 14 but even those claims lack a step that is specifically directed to deciding what is diagnostic for CML. For example, claim 13 produces a "distinctively altered" staining pattern but does not contain a step directed to then diagnosing CML. Claim 22 and claims dependent therefrom cite probes that are diagnostic for CML but,

in conflict, only cite regions of chromosomes 9 and/or 22 without discussing the diagnostic feature of said probes. It is noted that claim 42 is the first claim that cites a diagnostic determination. Clarification is requested as to what diagnostic practice is meant to be included within the scope of the above rejected claims.

Claim 26 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Since claim 26 cites all of the rearrangements instantly disclosed with regard to CML, there does not appear to be any further limitation that exists by the practice of claim 26 versus claim 22 from which claim 26 depends.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 10-19, 22, 24-26, 36-42, 45-48, 51-53, 74, 75, 102, 103, and 127-130 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 10-19, 22, 24-26, 36-42, 45-48, 51-53, 74, 75, 102, 103, and 127-130 of copending application Serial No. 07/497,098. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. This rejection is reiterated as applied in the previous office action mailed 7/28/92. It is noted that applicants have expressed the

intention to abandon application serial number 07/497,098 but that this rejection is still applicable because said abandonment has not been filed in 07/497,098 as of the mailing date of this office action.

Claims 10-12, 22, and 36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51, 112, and 114 of copending application Serial No. 07/627,707. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons already summarized in the previous office action mailed 7/28/92.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 24-26, and 102 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Groffen et al.

Groffen et al. discloses a 1.2 HBg probe in the legend of Figure 1 on page 94. This probe is a small hybridization probe that specifically hybridizes to the target region and thus appears to be free of repetitive nucleic acids. This probe is cited as being from chromosome 22 as given on page 93, second column, lines 29-34. The probe is labeled by nick translation as disclosed on page 98, second column, in the section entitled "Southern Blot Analysis" which reads on the heterogeneous limitation in the instant claims as well as also reading on the hybridization to two or more target sites as given in instant claim 24. The specific hybridization result as given in Figure 2 on page 94 meets the limitation of instant claim 25 in that non-targeted material is not hybridized by said probe since discrete hybridization bands are shown in said Figure 2. It is noted that instant claims 22, 24-26, and 102 do not contain the limitation to probes having a complexity of at least 35 kilobases.

The disclosure is objected to because of the following informalities:

On page 19, line 5, the word "earrangement" appears to be misspelled.

Starting on page 26 and going through page 33 the Brief Description of the Drawings discusses colored Figures. Unless very special arrangements are made the Figures will be printed in any allowed patent in black and white. Applicants are requested

to either delete the possibly confusing references to colors in the Figures or clearly indicate their intention to do what is necessary to product color Figures in any allowed patent resultant from the instant application.

On page 31-33, the sections of Figure 11 are discussed. This discussion of Figure 11 is however confusing in that the sections are denoted on pages 31-33 by the use of uncapitalized letters whereas the Figure 11 drawings use capitalized letters to denote each section. Clarification is requested that makes the letter designations uniform as to capitalization or not.

On page 58, the word "Labora- tories" is awkwardly hyphenated.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).
The CM1 Fax Center number is (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. MARSCHEL:am

October 28, 1992

MARGARET MOSKOWITZ
SUPERVISORY PATENT EXAMINER
GROUP 180